

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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The City of New York,	:	
	:	
Plaintiff,	:	
	:	
-against-	:	Case No. 1:23-cv-05880-LLS-OTW
	:	
Magellan Technology, Inc., et al.,	:	
	:	
Defendants.	:	
-----	X	

**MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF’S MOTION
FOR PRELIMINARY INJUNCTION FILED BY DEFENDANTS
MAGELLAN TECHNOLOGY, INC., ECTO WORLD, LLC,
MATTHEW J. GLAUSER, AND DONALD HASHAGEN**

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INTRODUCTION

The City of New York’s motion for preliminary injunction against Defendants Magellan Technology, Inc. (“Magellan”) Ecto World LLC d/b/a Demand Vape (“Demand Vape”), Matthew Glauser, and Donald Hashagen misstates the applicable standard of review, assumes facts for which the City has no evidence, omits or ignores other material facts, including as to the terms on which Demand Vape sells its products and the substantial public health benefits associated with e-cigarettes for users who would otherwise smoke combustible cigarettes, and improperly attempts to enforce the Federal Food, Drug, and Cosmetic Act. Predictably, the City falls far short of carrying its burden of proving a clear or substantial likelihood of success on the merits of its claims for violations of New York City Administrative Code § 17-715 or public nuisance.

Magellan and the individual Defendants cannot be found liable for violations of Section 17-715 because none of them possess, sell, or offer for sale any e-cigarette products to any person in New York City. Demand Vape similarly cannot be found liable for violating Section 17-715 because the facts and its terms of sale make clear that all of its sales are concluded in Buffalo, not New York City. The City simply cannot apply its laws extraterritorially.

Nor has the City carried its evidentiary burden of proving a substantial likelihood of success on its public nuisance claim. Hashagen has never had any involvement in any of the business activities of Magellan or Demand Vape and this Court lacks even personal jurisdiction over him. Glauser, while a principal of Magellan and Demand Vape, did not personally control or direct any corporate conduct allegedly causing the purported nuisance. The City provides no evidence that either Magellan or Demand Vape intended to promote or maintain sales of flavored ENDS products to underage individuals or had knowledge of any such illegal sales by their downstream customers, nor that they acted unreasonably in selling flavored ENDS products

exclusively through business-to-business transactions contemplated by both New York State and City law. Any causal linkage between Magellan and Demand Vape’s conduct and youth use of flavored e-cigarettes in New York City is far too attenuated when downstream retailers and/or individuals well outside Demand Vape or Magellan’s control must have necessarily violated multiple State and City laws without their knowledge for flavored e-cigarettes to end up in the hands of youth. Finally, the City fails to prove that the mere act of distributing flavored e-cigarettes is, in and of itself, injurious to the health of the City’s citizens—particularly when contrasted with the likely alternative of those citizens smoking far more harmful combustible cigarettes.

As explained herein, the City falls far short of the evidentiary showing required to justify the extraordinary remedy of a preliminary injunction. The City’s motion should be denied.

BACKGROUND

I. E-CIGARETTE USE GENERALLY

Electronic cigarettes are hand-held devices that enable a user to inhale an aerosol that contains nicotine.¹ Unlike traditional cigarettes, electronic cigarettes do not burn tobacco leaf or any other substance through combustion; rather, a nicotine-containing liquid (called “e-liquid”) is heated by a battery-powered heating element and aerosolized to create the resulting “vapor” that users can inhale.²

¹ Electronic cigarettes are also referred to as “e-cigarettes,” “electronic nicotine delivery systems” and “ENDS.”

² The photograph below from the U.S. Food and Drug Administration’s website shows examples of different types of electronic cigarettes:

Because electronic cigarettes do not expose users to toxins that are created by the burning of tobacco leaf, they present significantly fewer health risks than do traditional cigarettes. *See, e.g.*, National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes*, National Academies Press, Summary at 1 (2018) (“While e-cigarettes are not without health risks, they are likely far less harmful than combustible tobacco cigarettes.”); *accord Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 505 (6th Cir. 2021) (noting that e-cigarettes “may provide a beneficial alternative to combustible cigarettes because they deliver nicotine without also bombarding the user’s lungs with the toxins found in cigarettes”). In 2022, England’s Office for Health Improvement Disparities (“OHID”) concluded that “vaping poses only a small fraction of the risks of smoking,”³ and the Royal College of Physicians previously concluded that “the hazard to health arising from long-term vapour inhalation . . . is unlikely to exceed 5% of the harm from smoking tobacco.”⁴



³ Office for Health Improvement and Disparities (“OHID”) (formerly Public Health England), *Nicotine Vaping in England: 2022 evidence update summary* (2022), at ch. 16, <https://tinyurl.com/3njz34fd>.

⁴ Royal College of Physicians, *Nicotine without Smoke: Tobacco Harm Reduction* (2016), at 189, <https://tinyurl.com/22a2cz7x>.

For its part, the U.S. Food and Drug Administration (“FDA”) has stated that “[c]urrent scientific literature demonstrates that [electronic cigarettes] are generally likely to have fewer and lower concentrations of harmful and potentially harmful constituents (HPHCs) than combustible cigarettes, and biomarker studies demonstrate significantly lower exposure to HPHCs among current exclusive [electronic cigarette] users than current smokers.”⁵ An analysis of national sales data suggests that for every additional per-capita e-cigarette unit sold, combustible cigarette sales decline by 1.4 packs.⁶ Indeed, one study found that, if combustible cigarettes were replaced by e-cigarettes, between 1.6 million and 6.6 million U.S. lives would be saved over a ten-year period.⁷

According to the Centers for Disease Control (“CDC”), nearly six percent of U.S. adults currently use electronic cigarettes, whereas over eleven percent currently smoke combustible cigarettes.⁸ Nationally, an overwhelming majority of electronic cigarette users use non-tobacco flavored electronic cigarettes.⁹ And most adult electronic cigarette users are former or current

⁵ FDA, Sample Technical Project Lead Report of PMTAs at 10, <https://www.fda.gov/media/152504/download?attachment>.

⁶ Selya, et al., Sales of Electronic Nicotine Delivery Systems (ENDS) and Cigarette Sales in the USA: A Trend Break Analysis, J. CONSUM. POLICY (2023) 46:79-93, at 85, <https://tinyurl.com/bdfdwmys>.

⁷ David T. Levy, et al., *Potential deaths averted in USA by replacing cigarettes with e-cigarettes*, Tobacco Control 2017, available at <https://tobaccocontrol.bmj.com/content/27/1/18>.

⁸ CDC, National Center for Health Statistics, *Early Release of Selected Estimates Based on Data from the 2022 National Health Interview Survey* (Apr. 23, 2023), <https://perma.cc/D25X-2ASE>.

⁹ See *Wages and White Lion Investments L.L.C. v. FDA*, No. 21-60766, Joint Appendix at 88 (5th Cir. Jan. 14, 2022) (FDA Technical Project Lead (TPL) Review of PMTAs issued to Wages & White Lion Investments LLC (citing Schneller LM, Bansal-Travers M, Goniewicz ML, McIntosh S, Ossip D, O’Connor RJ. Use of Flavored E-Cigarettes and the Type of E-Cigarette Devices Used among Adult and Youth in the US-Results from Wave 3 of the Population Assessment of Tobacco and Health Study (2015-2016). *Int J Environ Res Public Health*. 2019; 16(16))) (FDA stating that approximately 77% of adult electronic cigarette users use non-tobacco flavored electronic cigarettes).

combustible cigarette smokers, including 92.8% of users over 45 years old—the age group most susceptible to near-term adverse health impacts from smoking combustible cigarettes.¹⁰

Despite the significant public health harm reduction potential of electronic cigarettes—including flavored electronic cigarettes—both the State and the City of New York have banned the retail sale of flavored electronic cigarettes to consumers. *See* N.Y. Pub. Health Law § 1399-mm-1; N.Y.C. Admin. Code § 17-715. Although such flavor bans are motivated by concerns that flavors attract youths to e-cigarettes, emerging scientific literature suggests that, on balance, flavor bans may do more harm than good, as they correlate both with increased consumption of combustible cigarettes and increased youth use of combustible cigarettes. One recent study conducted by FDA-funded researchers at Yale University’s School of Public Health concluded that “any public health benefits of reducing [e-cigarette] use via flavor restrictions may be offset by public health costs from increased cigarette sales.”¹¹ Those researchers analyzed the effects in 7 states and 375 localities that banned flavored e-cigarette products using five years of cigarette sales data, and found that flavored e-cigarette product bans resulted in an increased sale of 15 cigarettes for every banned 0.7ml flavored e-cigarette cartridge not sold because of the flavor restrictions.¹² A previous study of San Francisco’s flavor ban also found that the ban resulted in a

¹⁰ CDC, *QuickStats: Percentage Distribution of Cigarette Smoking Status Among Current Adult E-Cigarette Users, by Age Group—National Health Interview Survey* (Mar. 10, 2023), <https://perma.cc/TYR8-9KUV>.

¹¹ A. Friedman, et al., *E-cigarette Flavor Restrictions Effects on Tobacco Product Sales* (Sept. 26, 2023), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4586701.

¹² *Id.*

significant increase in adolescent smoking of combustible cigarettes that was not replicated in jurisdictions that had not enacted e-cigarette flavor bans.¹³

In 2021, fifteen past presidents of the staunchly anti-tobacco Society for Research on Nicotine and Tobacco (SRNT), the world's most highly regarded scientific society on tobacco and nicotine, published an essay in the American Journal of Public Health that, in part, addressed several assumptions advanced as rationales for flavor bans.¹⁴ Emphasizing that 1 out of every 7 U.S. adults is a combustible cigarette smoker and that smoking claims the lives of 480,000 Americans annually,¹⁵ the SRNT presidents emphasized their belief that “vaping can benefit public health, given substantial evidence supporting the potential of vaping to reduce smoking’s toll.”¹⁶

The past presidents warned that:

To date, the singular focus of US policies on decreasing youth vaping may well have reduced vaping’s potential contribution to reducing adult smoking. Those policies include . . . decreasing adult access to flavored e-cigarettes that may facilitate smoking cessation and convincing the public—including smokers—that vaping is as dangerous as smoking.¹⁷

¹³ Abigail S. Friedman, A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California, JAMA PEDIATR. 2021;175(8):865-867, Figure 1 at 864, <https://tinyurl.com/56z35ka7>; Abigail S. Friedman, Clarification and Correction of Survey Wave Collection Dates in an Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California, JAMA PEDIATR. 2022;176(9):1-4, at 1, <https://tinyurl.com/2p89r9cn>.

¹⁴ Balfour, David J. K., Neal L. Benowitz, Suzanne M. Colby, Dorothy K. Hatsukami, Harry A. Lando, Scott J. Leischow, Caryn Lerman, Robin J. Mermelstein, Raymond Niaura, Kenneth A. Perkins, Ovide F. Pomerleau, Nancy A. Rigotti, Gary E. Swan, Kenneth E. Warner, and Robert West: *Balancing Consideration of the Risks and Benefits of E-Cigarettes*, American Journal of Public Health 2021; 111(9):1661-1672, <https://doi.org/10.2105/AJPH.2021.306416>.

¹⁵ *Id.* at 1667.

¹⁶ *Id.* at 1662.

¹⁷ *Id.* at 1666.

Questioning “whether, for youth as a whole, vaping creates dangerous levels of nicotine exposure that would not have occurred in the absence of vaping,” the SRNT presidents stated:

Among those [young people] who vape, most do so infrequently; many are short-term experimenters. Frequent vaping is most common among current or former smokers, individuals already exposed to nicotine. The most dangerous form of youth exposure to nicotine, cigarette smoking, has declined at an unprecedented rate during the era of youth vaping. Use of other tobacco products has declined as well.¹⁸

The past presidents concluded that “[v]aping likely addicts some young people to nicotine. However, the evidence does not suggest it is addicting very large numbers.”¹⁹

Finally, the past presidents cast doubt on the City’s claims that youth nicotine use leads to adverse consequences for brain development or broadly serves as a “gateway” to combustible cigarette use:

[S]tudies lead some researchers to suspect that adolescent nicotine use in any form may lead to long-term structural and functional brain changes with associated negative implications for cognition or impulse control. However, given species differences and questions about the relevance of experimental animal nicotine dosing paradigms to human use patterns, the validity of extrapolation to humans is speculative. Whether impaired brain development with behavioral consequences occurs in young nicotine consumers is difficult to determine because of potential confounding of genetic and socioeconomic factors, the influence of other substance abuse, and the role of preexisting neuropsychiatric problems associated with youth smoking.

. . . .

If vaping causes some young people to try cigarettes, the aggregate impact must be small. A recent study estimated that if vaping increases non-smoking youths’ odds of trying cigarettes by 3.5 (as reported by *Soneji et al.*), smoking initiation among young adults would increase less than 1 percentage point. Furthermore, U.S. survey data demonstrate that smoking among young people has declined at its fastest rate ever during vaping’s ascendancy. If vaping increases smoking initiation, other unknown factors more than compensate.²⁰

¹⁸ *Id.* at 1665.

¹⁹ *Id.* at 1664.

²⁰ *Id.* at 1665.

Contrary to the City’s claims that there are “ever-increasing sales” of e-cigarettes to young people, ECF 50 at 4, the Center for Disease Control’s annual National Youth Tobacco Survey suggests that, nationally, youth usage of e-cigarettes is trending sharply *downward*. In 2019, at the height of popularity of JUUL-branded e-cigarettes, 27.5% of high school students reported using an e-cigarette at least once in the last 30 days.²¹ However, by 2022, that figure had dropped to 14.1%, and then again to 10.0% in 2023.²² In 2023, Hyde e-cigarettes—a brand owned by Defendant Magellan—were not identified on the NYTS as a brand used by youth.²³

The results of the biennial New York Youth Tobacco Survey are consistent with this national trend. E-cigarette use by New York youth declined from a peak of 27.4% in 2018 to 22.5% in 2020 and 18.7% in 2022.²⁴ Equally significantly, combustible cigarette use among New York youth, which stood at 27.1% in 2000 and 14.7% in 2008, when e-cigarettes were first introduced in the United States, had plummeted to 2.1% by 2022.²⁵

²¹ See Wang TW, et al. *Tobacco Product Use and Associated Factors Among Middle and High School Students – United States, 2019*, MMWR Surveill Summ 2019; 68 (No. SS-12:1-22), available at <https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm#>.

²² See Birdsey J, et al., *Tobacco Product Use Among U.S. Middle and High School Students – National Youth Tobacco Survey, 2023*, MMWR Morb Mortal Wkly Rep 2023; 72:1173-1182 (November 2, 2023), available at <https://perma.cc/XE7U-D5F4>.

²³ *Id.*

²⁴ N.Y. State Department of Health, Bureau of Tobacco Control, *Youth Tobacco Use Continues to Decline Across All Product Types in 2022, One in Five Youth Still Use Tobacco* (May 2023), https://www.health.ny.gov/prevention/tobacco_control/reports/statshots/volume15/n1_youth_tobacco_use.pdf.

²⁵ *Id.*

II. GOVERNMENT REGULATION OF ELECTRONIC CIGARETTES

A. FDA Regulation of Electronic Cigarettes.

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (“TCA”) to grant FDA authority over tobacco products. Pub. L. No 111-31, 123 Stat. 1776 (2009). The TCA defined a “tobacco product,” in relevant part, as “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product.” 21 U.S.C. § 321(rr) (2009).

Although the TCA originally applied only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, Congress authorized FDA to promulgate rules “deeming” other tobacco products to be subject to the Act. 21 U.S.C. § 387a(b). In 2016, FDA implemented a rule that deemed electronic nicotine delivery systems (“ENDS”), or e-cigarettes, to be subject to the Act. 81 Fed. Reg. 28973 (May 10, 2016).

However, because millions of electronic cigarettes were already on the market before August 2016, FDA’s policy has been to exercise “enforcement discretion” for electronic cigarettes, initially for any product on the market prior to August 8, 2016, and then for e-cigarettes with timely filed premarket tobacco product applications (“PMTAs”) seeking formal marketing authorization from FDA pursuant to Section 910 of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 387j, so long as those PMTAs are undergoing FDA review. *See generally, Vapor Tech. Ass’n v. FDA*, 977 F.3d 496 (6th Cir. 2020).²⁶ Indeed, FDA has never initiated an enforcement action against an electronic cigarette that is the subject of a PMTA undergoing FDA review and

²⁶ As it has done for e-cigarettes, FDA often exercises “enforcement discretion”—*i.e.*, refrains from bringing an enforcement action—for regulated products that do not have FDA marketing authorization. *See, e.g.*, FDA Compliance Policy Guide § 440.100 (describing how FDA “intend[s] to exercise [its] enforcement discretion with regard to drugs marketed in the United States that do not have required FDA approval for marketing”).

continues to allow the importation of e-cigarettes into the United States so long as a PMTA is pending for the subject products.²⁷

Prior to April 15, 2022, ENDS products containing nicotine that was synthetically manufactured or otherwise not derived from tobacco plants did not qualify as “tobacco products” and were not subject to the FDCA’s premarket authorization requirements because the statutory definition of a “tobacco product” extended only to products “made or derived from tobacco.” 21 U.S.C. § 321(rr) (2009). However, the Consolidated Appropriations Act, 2022, Pub. L. 117-103, 136 Stat. 49, Division P, Title I, Subtitle B, §111(a) expanded the statutory definition to include products containing nicotine “from any source” effective April 15, 2022. As a result, manufacturers of ENDS products were newly required to submit premarket tobacco applications for these synthetic nicotine products.²⁸

To date, FDA has granted marketing authorization for a few tobacco-flavored electronic cigarettes.²⁹ FDA has not yet granted marketing authorization for any non-tobacco-flavored electronic cigarettes, such as those flavored like fruit or menthol, but PMTAs for millions of such

²⁷ FDA has historically initiated two types of enforcement actions—civil money penalty actions and injunction actions—for the distribution of unauthorized electronic cigarettes. *See* <https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products#a>. FDA has also issued “Warning Letters” for the distribution of unauthorized electronic cigarettes. *Id.* But FDA’s position is that Warning Letters are “advisory” only and “are not final agency action” that can be challenged in court. *See* FDA Regulatory Procedures Manual, Chapter 4 at 4 (Jun. 2022); *accord Holistic Candlers & Consumers Ass’n v. FDA*, 664 F.3d 940 (D.C. Cir. 2012) (holding that an FDA Warning Letter was not subject to judicial review).

²⁸ The earlier submission deadline for PMTAs for ENDS products containing nicotine derived from tobacco plants was September 9, 2020. *See Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1135 (5th Cir. 2021).

²⁹ *See* <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>.

e-cigarette products remain pending with the agency.³⁰ Among the applications accepted by FDA and currently awaiting or under review are applications for many of Magellan’s flavored Hyde disposable electronic cigarettes. Declaration of Matthew J. Glauser (“Glauser Decl.”), ¶ 5.

FDA has the statutory authority to adopt a regulation through notice-and-comment rulemaking that would ban non-tobacco-flavored electronic cigarettes. *See* 21 U.S.C. § 387g(c). However, to adopt such a regulation, FDA would have to establish that banning flavored electronic cigarettes would result in a net benefit to the public health. *See id.* § 387g(a)(3)(A). FDA has never proposed, let alone adopted, such a regulation.

B. New York State and New York City Regulation of Electronic Cigarettes.

New York State law allows the sale of electronic cigarettes, including flavored electronic cigarettes, to “vapor product dealers” who are licensed by the State. *See* N.Y. Pub. Health Law § 1399-ll(1), (1-a).³¹ New York State law also allows the sale of tobacco-flavored electronic cigarettes to retail customers who are at least 21 years old, but prohibits the sale of non-tobacco-flavored electronic cigarettes to retail customers of any age. *See* N.Y. Pub. Health Law §§ 1399-bb(4), 1399-mm-1(2).

Like the State, New York City law permits the sale of tobacco-flavored electronic cigarettes to retail customers who are at least 21 years old and prohibits the sale of flavored electronic cigarettes. *See* N.Y.C. Admin. Code §§ 17-706(a-1), 17-715(1). However, New York

³⁰ *See* FDA, Tobacco Product Applications: Metrics and Reporting, <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting> (updated Nov. 3, 2023) (reporting that FDA has “accepted” premarket applications for over 6.7 million e-cigarette products and only issued marketing denial orders for approximately 1.24 million of those products).

³¹ “Vapor products” include electronic cigarettes. N.Y. Pub. Health Law § 1399-aa(17). A “vapor products dealer” is a “person licensed by the commissioner of taxation and finance to sell vapor products in this state.” N.Y. Pub. Health Law § 1399-aa(18).

City law expressly permits flavored electronic cigarettes to “be sold or offered for sale by wholesalers where the sale or offer for sale is made to an entity located outside the City.” 24 R.C.N.Y. § 28-02(b).

III. DEFENDANTS’ ROLES AND OPERATIONS

Defendant Magellan is the owner of the JUNO and Hyde trademarks and brands of electronic cigarettes. Glauser Decl., ¶ 4. Magellan is based in Buffalo, New York and is owned in part by Defendant Matthew J. Glauser, a resident of Buffalo. *Id.*, ¶¶ 3, 7. Magellan purchases electronic cigarette products from both U.S.- and foreign manufacturers and holds its inventory of those products at its warehouses in Buffalo. *Id.*, ¶ 9. All of Magellan’s operations are in Buffalo; it does not have any officers, employees, inventory, or operations in New York City. *Id.*, ¶ 7. Magellan does not engage in the sale of any e-cigarette products or e-liquids, flavored or unflavored, to any person other than its affiliate, Defendant Demand Vape. *Id.*, ¶ 10. Those sales also occur exclusively in Buffalo. *Id.*

Magellan has submitted multiple PMTAs to FDA for its JUNO and Hyde e-cigarette products. Glauser Decl., ¶ 5. While FDA issued Magellan a marketing denial order for several flavored JUNO e-cigarette cartridges in 2021 that is the subject of ongoing litigation between Magellan and FDA, those products have not been sold in the United States since early 2020. *Id.* Magellan also has applications for numerous flavored Hyde disposable e-cigarette products that are pending with FDA. *Id.*

Demand Vape is similarly headquartered in and operates exclusively in Buffalo, New York. Glauser Decl., ¶ 7. All of Demand Vape’s employees, officers, and warehouses are based there; none are based in New York City. *Id.* Demand Vape stores its inventory of electronic cigarette products and e-liquids in Buffalo, sells them from Buffalo, and ships them from Buffalo to its customers nationwide and internationally. *Id.*, ¶¶ 7, 14. None of Demand Vape’s inventory

is stored in, sold from, or shipped from New York City. *Id.*, ¶ 14. Demand Vape requires that, before any customer that is a retailer can place an order, the customer must provide Demand Vape with a copy of its active New York State vapor product dealer's registration certificate required by New York Tax Law § 1183. *Id.*, ¶ 15.

Demand Vape engages exclusively in the business-to-business sale of electronic cigarettes and e-liquids; it has not engaged in the sale of any electronic cigarettes or e-liquids to consumers or customers that provide residential addresses since at least 2020. Glauser Decl., ¶ 11. While Demand Vape operates the website hydedisposables.com, that website is for informational purposes only and no sales are made or processed through the website. *Id.*, ¶ 12. Demand Vape's invoices, which must be paid before Demand Vape will ship products to a customer, include the following term: "The sale is completed once goods are shipped from our facility." *Id.*, ¶ 13; *see also* Demand Vape Invoices to Star Vape Corp., Exhibit S to Proshansky Declaration, ECF 42-2.

In addition to being a partial owner of both Magellan and Demand Vape, Glauser is an officer of both corporate entities. Glauser Decl., ¶¶ 3, 6. That said, he does not personally engage in the sale of e-cigarette or e-liquid products, but rather leaves such activities to Demand Vape's account representatives, and has never personally negotiated for or directed any specific sales of e-cigarette products to a customer of Demand Vape in New York City. *Id.*, ¶ 8. Glauser also owns a Virginia limited liability company that the City has not named as a defendant, Firmitas Solutions, LLC ("Firmitas"). Firmitas, which is based in Henrico, Virginia, is a contract manufacturer of e-liquids. *Id.*, ¶ 20. Firmitas, however, has no involvement in the sale or offer for sale of any e-liquid or other e-cigarette products to any customers in New York City. *See* Declaration of Donald Hashagen ("Hashagen Declaration"), ECF 55, at ¶¶ 15-16.

Defendant Donald Hashagen is a citizen and resident of Virginia and the executive vice president of Firmitas, where he manages contract service, sales, and manufacturing operations. Glauser Decl., ¶ 21; Hashagen Decl., ¶ 4. Hashagen has never had any involvement in the activities of either Magellan or Demand Vape and was never an owner, officer, director, or employee of either entity, never had any authority to make any business decisions on behalf of either entity, has never received any compensation from either entity, and knows nothing about any sales of any e-cigarette products by either entity to anyone in New York City. Glauser Decl., ¶ 21; Hashagen Decl., ¶ 14. Indeed, Hashagen has moved to dismiss the City's claims against him based on a lack of personal jurisdiction, ECF 54, as he does not reside in New York, owns no property or business in New York, has never worked in New York, and has not even visited New York in at least three years. Hashagen Decl., ¶¶ 2-3.

None of the Defendants own, operate, or control any distributor or retailer of e-cigarette products in New York City. Glauser Decl., ¶ 16. Neither Magellan nor Demand Vape has ever sold any e-cigarette products to the seven New York City retailers listed in footnote 10 of the City's memorandum: Yolo Smoke City, Convenience of Columbus, Morris Park Convenience Store, Garden Fresh Gourmet Deli, Hookah 2 Plus, LA Convenience Store, or XXX Vape Shop. *Id.*, ¶¶ 10, 17. Empire Vape has also never been a customer of either Magellan or Demand Vape. *Id.*, ¶¶ 10, 17.

Neither Glauser, Magellan, nor Demand Vape have ever had any specific knowledge of illegal sales to youth by any of Demand Vape's customers in New York City. *Id.*, ¶ 18. However, given the concerns raised by the City, Demand Vape has instituted a formal, company-wide policy prohibiting the sale of flavored e-cigarettes to any retailers based in New York City. *Id.*, ¶ 19.

STANDARD OF REVIEW

“A preliminary injunction is an extraordinary remedy never awarded as of right.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). To establish entitlement to the drastic remedy of a preliminary injunction, a plaintiff must establish: (1) that it is likely to succeed on the merits; (2) that it will be irreparably injured if the relief sought is not granted; (3) that a balance of the hardships tips decidedly in the plaintiff’s favor; and (4) that an injunction would be in the public interest. *Id.* at 20; *JTH Tax, LLC v. Agnant*, 62 F.4th 658, 667 (2d Cir. 2023).

“In at least two circumstances, a plaintiff seeking a preliminary injunction must satisfy a heightened standard by ‘showing a clear or substantial likelihood of success on the merits, and by making a strong showing of irreparable harm.’” *JTH Tax*, 62 F.4th at 667 (quoting *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 650 (2d Cir. 2015)). First, this heightened standard applies if the plaintiff seeks an injunction that provides it substantially all the relief the plaintiff seeks in the litigation, and the relief cannot be meaningfully undone in the event that the enjoined party prevails on the merits. *Id.* (citing *Tom Doherty Assocs., Inc. v. Saban Ent., Inc.*, 60 F.3d 27, 34-35 (2d Cir. 1995)). Second, the heightened standard applies if the plaintiff seeks a “mandatory injunction”—“an injunction that ‘alters the status quo.’” *Id.*³² A mandatory injunction can be stated in terms either compelling action or prohibiting action. *See SEC v. Unifund SAL*, 910 F.2d 1028, 1040 (2d Cir. 1990) (imposing “substantial likelihood of success” standard because “though the order [prohibiting future securities laws violations] is prohibitory in form, rather than mandatory, it accomplishes significantly more than preservation of the status quo”); *Manigault v. ABC Inc.*, No. 17-cv-7375, 2018 U.S. Dist. LEXIS 112766, *3 (S.D.N.Y. June 21, 2018) (applying

³² Conversely, a “prohibitory” injunction, “seeks only to maintain the status quo pending a trial on the merits” and is not subject to the heightened standard. *Tom Doherty Assocs.*, 60 F.3d at 33-34.

heightened standard because movant requested that “the Court alter the status quo by directing the defendant to refrain from certain acts; thus the nature of the injunction sought [was] mandatory, notwithstanding the prohibitory form”).

Here, the City seeks a “mandatory” injunction that would alter the status quo by requiring Defendants to cease all sales to New York City-based companies, including distributors that lawfully sell flavored e-cigarettes to other distributors and retailers outside of New York City. Therefore, the City must demonstrate a “clear or substantial likelihood of success on the merits” to establish entitlement to injunctive relief. *See, e.g., City of New York v. Golden Feather Smoke Shop, Inc.*, 597 F.3d 115, 121 (2d Cir. 2010) (holding that “[t]he City must make a ‘clear’ and ‘substantial showing of a likelihood of success, both as to violation and risk of recurrence’ for its statutory claims because the injunction sought was mandatory”).^{33, 34}

ARGUMENT

I. The City Has Not Shown a Clear or Substantial Likelihood of Success on the Merits

A. Only the FDA, and Not the City, Has Sole Authority and Discretion to Enforce the Federal Food, Drug, and Cosmetic Act.

Throughout the City’s memorandum in support of its motion, the City repeatedly claims that Defendants are engaged in sales of flavored e-cigarettes products that are “adulterated” and

³³ The City’s citation to *Golden Feather Smoke Shop* on page 20 of the City’s brief is misleading. While the Second Circuit cited in passing the “general” standard of a “likelihood of success on the merits,” 597 F.3d at 120, the court actually *applied* the more demanding “clear or substantial” likelihood of success standard because the City there sought a mandatory injunction analogous to that which the City seeks here, *id.* at 121.

³⁴ The City’s contention in footnote 23 of its memorandum that the “substantial likelihood of success” standard applies *only* if the requested injunction would provide substantially all of the relief sought in the complaint is incorrect. As the Second Circuit recently confirmed in *JTH Tax*, the higher standard is also equally applicable where, as here, the injunction sought is “mandatory” in nature and would alter the status quo. 62 F.4th at 667.

illegal under the Federal Food, Drug, and Cosmetic Act (“FDCA”). *See* ECF 50 at 1, 2 n.3, 3, 4, 10 n.14, 11-13, 14-15, 16 & n.20, 19 n.21, 26, 32, 33 & n.33, 34. However, *only* FDA, and not any other private or governmental actor, including the City, has authority to enforce the provisions of the FDCA. Title 21 U.S.C. § 337(a) provides that “all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.” Section 337(a) thus “leaves no doubt that it is the federal government rather than private litigants who are authorized to file suit for noncompliance with the [provisions of FDCA],” including, in this case, Section 910’s tobacco product premarket review requirement. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 344 (2001); *see also POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014) (“[T]he FDCA and its regulations provide the United States with nearly exclusive enforcement authority. . . . Private parties may not bring enforcement suits.”); *Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 476 (D.N.J. 1998) (citing cases) (“Only the federal government, by way of either the [FDA] or the Department of Justice, has exclusive jurisdiction to enforce violations of the [FDCA].”).³⁵ The same principle applies to attempts by other governmental agencies to enforce the FDCA’s requirements. *See, e.g., People of the State of New York v. JUUL Labs, Inc.*, No. 452168/2019, 2022 N.Y. Misc. LEXIS 11127, **31-33 (N.Y. Cnty. July 5, 2022) (holding claim under Executive Law § 63(12) premised on alleged violations of Section 911 of the FDCA, 21 U.S.C. § 387k, impliedly preempted by FDCA and granting motion to dismiss). The rationale for this enforcement regime is simple – if a private right of action were recognized, “the

³⁵ *See also PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.), *cert. denied*, 513 U.S. 965 (1994) (citing *Pac. Trading Co. v. Wilson & Co., Inc.*, 547 F.2d 367, 370 (7th Cir. 1976), and holding that “violations of the FDCA do not create private rights of action”); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), *cert. denied*, 510 U.S. 1197 (1994) (citing the same principle); *Ginocchio v. Surgikos, Inc.*, 864 F. Supp. 948, 956 (N.D. Cal. 1994) (citing various courts that have held that “there is no private cause of action for violation of the Food, Drug, and Cosmetic Act.”).

major advantages of enforcement through the [FDA] would be lost, including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a unitary enforcement policy.” *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995) (citation omitted).

FDA possesses “a variety of enforcement options that allow it to take a measured response to suspected” violations of the FDCA. *Buckman*, 531 U.S. at 349; *see also* 21 U.S.C. §§ 331(a)-(d), 332, 333, 334, 336 (providing, *inter alia*, authority to issue warning letters, initiate civil injunction actions against violators, seize violative products, seek civil money penalties, and pursue criminal prosecution of individuals and companies).³⁶ “[F]lexibility is a critical component

³⁶ The City’s memorandum is replete with errors and omissions related to FDA’s implementation and enforcement of the FDCA and its premarket authorization requirement, including as to Magellan’s products. For example, the City’s memorandum references a supposed “October 12, 2018 FDA warning letter to ‘sister company’ Magellan.” ECF at 10, 14. FDA issued a letter to Magellan seeking information regarding certain *JUNO* products dated October 12, 2018, *see* Exhibit Q to Proshansky Declaration, ECF 42-2, but that letter was definitively *not* an FDA Warning Letter.

The City has also submitted an FDA marketing denial order dated September 8, 2021, addressed to Magellan that was for *JUNO-branded* flavored e-cigarette products which neither Magellan nor Demand Vape has sold anywhere in the United States since early 2020. *See* Exhibit A to Proshansky Declaration, ECF 42-1, at JA 11; Glauser Decl., ¶ 5. The marketing denial order is the subject of ongoing litigation between Magellan and FDA, with Magellan having recently received an extension from Justice Sotomayor to petition for certiorari on the Second Circuit’s denial of Magellan’s petition for review of the marketing denial order. Contrary to the City’s erroneous claims, ECF 50 at 11, FDA has never issued a marketing denial order for any of Magellan’s Hyde-branded e-cigarette products or found that those products lack “sufficient evidence to meet the ‘net benefit’ standard required by the Tobacco Control Act.” ECF 50 at 11; Glauser Decl., ¶ 5. In reality, Magellan has multiple premarket applications that currently remain pending with FDA for flavored Hyde products. Glauser Decl., ¶ 5.

The City likewise claims that “R.J. Reynolds’ Vuse and Altria’s Juul” are two “principal, FDA-approved, legal e-cigarette brands.” ECF 50 at 15. In reality, FDA has never granted marketing authorization for *any* Juul products or R.J. Reynolds’ most popular and best-selling e-cigarette, the Vuse Alto, and, in fact those products have been subject to marketing denial orders issued by FDA and contested by the applicants. *See* FDA, Premarket Tobacco Product Marketing Granted Orders, <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>.

of the statutory and regulatory authority under which the FDA pursues difficult (and often competing) objectives.” *Buckman*, 531 U.S. at 349. The FDCA’s “enforcement provisions thus commit *complete discretion* to [FDA] to decide how and when they should be exercised.” *Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (emphasis added).

Without a private right of action to enforce the FDCA, the exclusive remedy for a party that disagrees with FDA’s discretionary enforcement decisions or who seeks to enforce the FDCA is to file a “citizen petition” with FDA, which will make its own decision on enforcement action. *See* 21 C.F.R. §§ 10.25, 10.30. As the Supreme Court pointed out in *Buckman*, the FDA is empowered to investigate suspected violations of FDCA, *see* 21 U.S.C. § 372; 21 C.F.R. § 5.35, and citizens may report wrongdoing and petition the agency to take action, 21 C.F.R. § 10.30. 531 U.S. at 349.

The prohibition on private FDCA enforcement actions extends to attempts by litigants other than FDA to use other laws to indirectly enforce alleged violations of the FDCA. *See, e.g., PhotoMedex*, 601 F.3d at 924 (“Because the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation.”); *Amarin Pharma, Inc. v. ITC*, 923 F.3d 959, 966 (Fed. Cir. 2019) (dismissing alleged unfair competition claim under Tariff Act based on alleged violations of FDCA and holding preclusion applies “where th[e] claim is based on proving violations of the FDCA and where the FDA has not taken the position that the articles at issue do, indeed, violate the FDCA”); *Mylan Labs.*, 7 F.3d at 1139 (“[P]ermitting Mylan to proceed on the theory that the defendants violated § 43(a) merely by placing their drugs on the market, would in effect permit Mylan to use the Lanham Act as a vehicle by which to enforce the

[FDCA] and the regulations promulgated thereunder.”); *JUUL Labs*, 2022 N.Y. Misc. LEXIS 11127, at **31-33 (dismissing claim under Executive Law § 63(12)).³⁷ This is true regardless of whether the claims are asserted under federal or state law. *See, e.g., Summit II*, 933 F. Supp. at 943, n.21 (prohibiting plaintiff from bringing a claim under state unfair competition law); *National Women’s Health Network*, 545 F. Supp. 1177, 1181 (D. Mass. 1982) (“A private right of action is equally inconsistent with the federal regulatory scheme, whether the right is based on federal or state law.”); *Yimam v. Myle Vape, Inc.*, No. 2019 CA 008050 B, 2020 D.C. Super. LEXIS 7, (D.C. Super. Ct. June 11, 2020) (granting motion to dismiss because alleged violations of the FDCA were a “critical” element of alleged state consumer protection and unfair trade practice claims and were therefore preempted by FDCA).

Here, as noted above, when FDA extended its jurisdiction by regulation over certain e-cigarette products in 2016, as the Agency does with many other products it regulates, FDA initiated a policy of “enforcement discretion” for electronic cigarettes—both flavored and unflavored—with timely-filed pre-market applications. As a result, FDA has never initiated an enforcement action regarding an electronic cigarette—including a flavored electronic cigarette—that is the subject of a PMTA undergoing FDA review and continues to allow the importation of e-cigarettes into the United States so long as they are the subject of pending PMTA.

Despite the City’s misleading claims that FDA has “banned flavored e-cigarette pods” and that there is a “federal flavor ban,” ECF 20, at ¶¶ 53-54, FDA has never enacted a tobacco product standard regulation “banning” flavored e-cigarette products as would be required under 21 U.S.C.

³⁷ *Accord Eli Lilly & Co.*, 23 F. Supp. 2d at 476; *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990) (Lanham Act); *Autin v. Solvay Pharms., Inc.*, No. 05-2213, 2006 U.S. Dist. LEXIS 19507 (W.D. Tenn. May 31, 2006); *Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996) (“*Summit I*”) and 933 F. Supp. 918, 933 (C.D. Cal. 1996) (“*Summit II*”).

§ 387g(a)(3)-(4). Rather, in early 2020, FDA merely modified the contours of its deferred enforcement policy to remove flavored cartridge-based (or “pod”) e-cigarettes from that policy and prioritize them for enforcement, while specifically exempting *disposable* e-cigarettes from that prioritization for enforcement.³⁸ Significantly, the City does not allege that Demand Vape or any of the Defendants sell any flavored, pod-based electronic cigarettes in New York City or elsewhere, nor could it, as Demand Vape has not done so since FDA issued that policy in 2020. *See* Glauser Decl., ¶ 5.

Because Congress empowered only FDA, and not the City, to enforce the FDCA’s requirements, to the extent that the City’s arguments regarding its likelihood of success on its public nuisance claim are premised on the City’s contentions that Demand Vape or any of the other Defendants are violating the FDCA by selling flavored e-cigarettes, the Court must ignore those allegations as legally irrelevant for purposes of deciding the City’s motion. 21 U.S.C. § 337(a).

B. The City Has Not Shown, and Cannot Show, that Defendants Have Violated New York City Administrative Code § 17-715.

Regardless of the evidentiary standard applied, the City has not shown, and cannot show, that Defendants have violated New York City Administrative Code § 17-715. As a threshold matter, in its operative First Amended Complaint, ECF 20, the City has not alleged an independent cause of action or claim based on Section 17-715. As a factual matter, Defendants have not sold and do not sell, offer for sale, or possess with the intent to sell or offer for sale any flavored e-cigarettes or flavored e-liquids in New York City.

³⁸ *See* FDA, Guidance for Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (2020), at 2-3, 18-21, and 9 n.21.

1. Defendants Magellan, Glauser, and Hashagen do not possess, sell, or offer for sale any e-cigarette products or e-liquids in New York City.

As noted above, Magellan does not engage in the sale of any e-cigarette products or e-liquids, flavored or unflavored, to any person other than its affiliate, Demand Vape, and those sales occur exclusively in Buffalo, New York. Magellan thus neither offers for sale nor possesses with the intent to sell or offer for sale such products in New York City. Jon Glauser, a principal of Magellan and Demand Vape who lives in Buffalo, likewise does not personally engage in any sales of e-cigarette or e-liquid products, much less do so in New York City; rather such sales occur exclusively through Demand Vape, which, like Magellan and Glauser, is also based in Buffalo, to its customers. For his part, Donald Hashagen, a citizen of Virginia who has not even traveled to New York in years, does not have, and has never had, any role in the business operations of either Magellan or Demand Vape. Thus, as a factual matter, there is no evidence or basis whatsoever to conclude that the City has any likelihood of proving that Magellan, Glauser, or Hashagen has ever violated Section 17-715 by selling, offering for sale, or possessing with intent to sell or offer for sale any flavored electronic cigarette or flavored e-liquid in New York City.

2. Defendant Demand Vape only possesses, sells, and offers for sale flavored e-cigarettes and e-liquids in Buffalo, not New York City.

For its part, as noted above, Demand Vape is headquartered and operates exclusively in Buffalo, New York. All of its employees, offices, and warehouses are based there; none are based in New York City. Demand Vape's inventory of e-liquids and flavored electronic cigarette products is stored at its warehouses in Buffalo, sold from there, and shipped from there to its customers nationwide and internationally; none of Demand Vape's inventory is stored in, sold from, or shipped from New York City.

Demand Vape engages exclusively in the business-to-business sale of electronic cigarettes and e-liquids; it has not engaged in the sale of any electronic cigarettes or e-liquids to consumers or customers that provide residential addresses since at least 2020. As noted above, the website cited by the City, hydedisposables.com, contains no restrictions on sales to New York City because no sales are made or processed through the website—whether to New York City or anywhere else. No person can purchase flavored e-cigarette products through Hydedisposables.com, regardless of the person’s location.

Demand Vape’s sales also take place exclusively in Buffalo, not New York City. Demand Vape’s invoices, including those the City itself filed in support of its motion, state as follows: “The sale is completed once goods are shipped from our facility.” *See* Demand Vape Invoices to Star Vape Corp., Exhibit S to Proshansky Declaration, ECF 42-2; Glauser Decl., ¶ 13. Title to the goods thus transfers in Buffalo, where Demand Vape’s facilities are located, not New York City, and the sale is completed in Buffalo. *See* N.Y.U.C.C. § 2-401(1) (providing that “title to goods passes from the seller to the buyer in any manner and on any conditions explicitly agreed on by the parties”).³⁹ Far from being a “facial violation” of Section 17-715, Demand Vape’s sales to Star Vape Corp., a “Wholesale B2B distributor” and the only evidence of actual

³⁹ Indeed, even if Demand Vape’s invoices did not contain the express term set forth above, New York law would still impose a strong presumption that Demand Vape’s sales contract with its customers is a “shipment contract” under which title passes to the purchaser at the time and place of shipment, *see* N.Y.U.C.C. § 2-504, —here, Buffalo—as opposed to a “destination contract” under N.Y.U.C.C. § 2-503(3). *See Windows Inc. v. Jordan Panel Sys. Corp.*, 177 F.3d 114, 116, 117 (2d Cir. 1999) (observing that “there is a strong presumption under the U.C.C. favoring shipment contracts” and that, under a shipment contract, the seller need merely “put the goods in the possession of such a carrier and make such a contract for their transportation as may be reasonable” (citing N.Y.U.C.C. § 2-504(a))).

sales offered to support the City’s motion, occurred in Buffalo, not New York City.⁴⁰ *See* Star Vape Website Print-Out, Exhibit A to the Declaration of Eric N. Heyer. Demand Vape has also not violated Section 17-715 by selling, offering for sale, or possessing with intent to sell or offer for sale any flavored electronic cigarette or flavored e-liquid in New York City.

The City has no likelihood of success on its unpleaded claim for violating New York City Administrative Code § 17-715 against any of Magellan, Glauser, Hashagen, or Demand Vape.

C. The City Has Not Shown a Substantial Likelihood of Success on its Public Nuisance Claim.

Nor has the City shown a substantial likelihood of success on its public nuisance claim against any of the Defendants. The City lacks any factual basis to posit a likelihood of success against the individual defendants. Glauser is merely a principal of the corporate defendants, Magellan and Demand Vape, and does not personally engage in the sale of any flavored e-cigarettes or e-liquids.⁴¹ And, as noted above, Hashagen has no involvement in the business

⁴⁰ Further, it is far from clear that sales to Star Vape, a wholesaler, would have necessarily violated Section 17-715 even if title had not transferred in Buffalo. The regulations adopted by the City’s Department of Health and Mental Hygiene to interpret and implement Section 17-715 specifically provide that flavored electronic cigarettes may be “sold or offered for sale by wholesalers where the sale or offer for sale is made to an entity located outside the City.” 24 R.C.N.Y. § 28-02(b). Section 28-02(b) can be reconciled with Section 17-715 if the latter’s prohibition on sales, offering for sale, and possession applies only to retail transactions and not to wholesale sales. As a practical matter, there would be no way for the New York City-based wholesalers contemplated by Section 28-02(b) to receive flavored e-cigarette products to sell to customers outside the City (unless they are also manufacturers) if Section 17-715 applied to sales to them.

⁴¹ An individual defendant as officer, employee, or member of a company is liable for the company’s intentional torts only if they participate in the commission of the tort in furtherance of company’s business. *See, e.g., Retropolis Inc. v. 14th Street Development*, 17 A.D.3d 209, 210 (App. Div. 1st Dept. 2005); *Rothstein v. Equity Ventures, LLC*, 299 A.D.2d 472, 474 (App. Div. 2d Dept. 2002). And even in the public nuisance context, the individual must “control[] corporate conduct [causing the public nuisance] and thus [be] an active individual participant in that conduct” to be liable for public nuisance caused by the corporation. *New York v. Juul Lab’ys.*, No. 452168/2019, 2022 N.Y. Misc. LEXIS 4983, at **28-29 (N.Y. Cnty. July 14, 2022).

activities of either entity or even minimum contacts with the State of New York that would subject him to personal jurisdiction here.

As for the corporate defendants, Magellan and Demand Vape, the City falls far short of satisfying its evidentiary burden of proving a “clear or substantial likelihood of success” on its public nuisance claim. *JTH Tax*, 62 F.4th at 667. Because the City cannot prove that Magellan or Demand Vape violated New York City Administrative Code § 17-715, it cannot prove a nuisance *per se* and thus is required to prove both that Magellan and Demand Vape intended to create, cause, or maintain a public nuisance *and* that they acted unreasonably. The City provides no evidence on either count and, indeed, cannot do so. Additionally, as to causation, the City is required to prove that Magellan and Demand Vape “participated to a substantial extent” in creating or maintaining the alleged nuisance. Again, however, the evidence adduced by the City falls far short of meeting this standard. Finally, the City’s alleged evidence that the mere distribution of flavored e-cigarettes and flavored e-liquids is, in and of itself, injurious to the health of the City’s citizens—particularly when contrasted with the alternative of smoking combustible cigarettes—is deficient.

1. The City fails to show that Magellan or Demand Vape’s actions were intentional or unreasonable.

First, the City does not, and cannot, show that Magellan or Demand Vape intended to create, cause, or maintain a public nuisance, nor that they acted unreasonably. The City proceeds on the predicate assumption that Magellan and Demand Vape have violated New York City Administrative Code § 17-715 and thus their conduct qualifies as a “nuisance *per se*.” ECF 50 at 27-28. However, as explained above, neither Magellan, which does not possess flavored e-cigarette and e-liquid products in New York City, offer such products for sale in New York City, or sell such products to anyone anywhere other than to its affiliate, Demand Vape, in Buffalo, nor Demand Vape, which sells its products on terms whereby the sale is concluded in Buffalo, has

violated Section 17-715. Because the City has not shown and cannot show a violation of Section 17-715, it cannot establish that any alleged conduct by Magellan or Demand Vape was a nuisance *per se*.

Instead, then, the City must establish that Magellan and Demand Vape’s conduct was *both* “intentional” and “unreasonable.” *See Suez Water N.Y. Inc. v. E.I. du Pont de Nemours & Co.*, No. 20-cv-10731 (LJL), 2023 U.S. Dist. LEXIS 48925, at *34 (S.D.N.Y. Mar. 22, 2023) (“Under New York law, a defendant who does not owe a duty to another and who does not engage in otherwise tortious conduct can still be liable for the harm caused to third parties if the defendant’s actions were intentional and unreasonable.”).

a. Magellan and Demand Vape did not act intentionally to promote e-cigarette use by youth or to otherwise contribute to a any alleged public nuisance.

“A defendant acts intentionally if it acts or fails to act with the *purpose* of interfering with a public right, knew that such interference was resulting or was substantially certain to result from its conduct, or became aware that its conduct was causing such interference and nevertheless continued it.” *Suez Water*, 2023 U.S. Dist. LEXIS 48925, at *35 (quoting *NAACP v. Acusport, Inc.*, 271 F. Supp. 2d 435, 449 (E.D.N.Y. 2003)) (emphasis added). “It is the knowledge that the actor has at the time he acts or fails to act that determines whether the invasion resulting from his conduct is intentional or unintentional. He must either act for the purpose of causing [the nuisance] or know that it is resulting or is substantially certain to result from his conduct.” *Id.* (quoting Restatement (Second) of Torts § 825 cmt. c).

A “general awareness that harm is resulting or likely to result” does not satisfy the intentionality requirement, nor is it enough that the defendant “realizes or should realize that his conduct involves a serious risk or likelihood of causing the invasion.” *Suez Water*, 2023 U.S. Dist.

LEXIS 48925, at *35 (quoting *City of New York v. Beretta U.S.A. Corp.*, 315 F. Supp. 2d 256, 278 (E.D.N.Y. 2004), and Restatement (Second) of Torts § 825 cmt. c).

Here, the City has adduced no evidence demonstrating that Magellan or Demand Vape ever intended to create, cause, or maintain sales of flavored e-cigarette products to underage youth, and the City simply cannot supply such proof because Defendants never had such an intent. Unlike in *In re MTBE Products Liability Litigation*, 725 F.3d 65, 121 (2d Cir. 2013), the City has produced no evidence or testimony showing that Magellan or Demand knew that any of their customers that purchased flavored e-cigarette products would sell them to underage youth. In *In re MTBE Prods. Liab. Litig.*, the defendant delivered MTBE-containing gasoline to underground storage tank systems at gas stations it owned and controlled and to additional service tanks that it knew would leak, even though it did not own or control them. *Id.* at 82, 88. Here, in contrast, Defendants do not own, operate, or control any distributor or retailer in New York City, nor did they have any specific knowledge of illegal sales to youth by any of their customers in the City. Glauser Decl., ¶ 18.

The City adduces no evidence of any sales by Magellan to any person located in New York City, nor could it, as Magellan's only customer is Demand Vape, which is based in Buffalo. For Demand Vape, the only evidence the City adduces of any actual sales to a customer based in New York City is of sales to Star Vape Corp., a wholesaler that under the City's own regulations interpreting Section 17-715 was allowed to possess and sell flavored e-cigarettes so long as it was to customers located outside of New York City. *See* 24 R.C.N.Y. § 28-02(b) ("Flavored electronic cigarettes and flavored e-liquids may only be sold or offered for sale by wholesalers where the sale

or offer of sale is made to an entity located outside the City of New York.”).⁴² This evidence thus provides no basis to conclude that Demand Vape intended for the products it sold to be sold to or consumed by underage youth or knew that such would be “substantially certain” to result from its sales to Star Vape.

Without any actual evidence of knowledge or intent on the part of Demand Vape or Magellan, the City instead attempts to rely on unsupported inferences and conclusory assertions to establish that Magellan and Demand Vape knew that sales to and consumption of flavored e-cigarette products by youth were substantially certain to result from their business-to-business sales. *See* ECF at 30. However, general awareness that youth, like adults, may prefer flavored e-cigarettes, or even a theoretical general awareness that the City apparently fails to adequately enforce its laws against sales to youth as described in the City’s supporting declarations, does not mean it is substantially certain that, by Magellan and Demand Vape selling their products, they themselves—rather than retailers located within the City itself—will be contributing to a purported public nuisance of youth purchase and use of those products.

The City intentionally conflates the potential foreseeability of a retailer violating the law and selling an e-cigarette to an underage consumer with “Defendants’ knowledge that [their] actions, either individually or in combination with the actions of others” would interfere with a public right. *Suez Water*, 2023 U.S. Dist. LEXIS 48925, at *40. To be liable, Defendants must have known or been “substantially certain” that their actions would result in the alleged public nuisance. *Id.* Suggesting, as the City does, that because Magellan sells its products to Demand

⁴² Notably, despite the City’s conclusory claim in its memorandum, ECF 50 at 31, that Magellan, Demand Vape, and Defendant Empire Vape “form a supply chain” that imports and distributes flavored e-cigarettes in the City, Empire is not, and has never been, a customer of either Magellan or Demand Vape. Glauser Decl., ¶ 17.

Vape, which, in turn, sells to businesses nationwide, both Magellan and Demand Vape must have been “substantially certain” that “young people” would acquire and use those products requires an impermissible leap of logic. The City’s evidence is simply insufficient to establish that Magellan or Demand Vape intentionally contributed to any alleged nuisance. *See Suez Water*, 2023 U.S. Dist. LEXIS 48925 at **45-46.

b. Magellan and Demand Vape did not unreasonably interfere with a public right.

Further, even if the Court could possibly conclude (which it cannot) that Magellan and Demand Vape acted intentionally, “it is insufficient that the defendant’s actions were intentional; in the absence of a duty, they must also be unreasonable . . . that is, ‘the gravity of the harm of the action outweigh the utility of the actor’s conduct.’” *Id.* at *36 (quoting and citing Restatement (Second) of Torts §§ 821B cmt. *e*; 822 & cmt. *a*; 826 & cmt. *a*) (cleaned up). Again, once the City’s ephemeral innuendo is discarded, what is left is a dearth of any concrete evidence that either Magellan or Demand Vape have acted unreasonably.

In arguing that “there is injury to the public health of [the City’s] citizens through the proliferation of e-cigarettes and e-liquids because those products incontrovertibly endanger the health of the City’s youth,” the City artificially cabins the public health inquiry around such products to focus exclusively on (illegal) sales to and use by youth and ignores the public health benefits of use by adults (and even to youth who would otherwise smoke combustible cigarettes⁴³). As noted above, the scientific consensus is that e-cigarettes are, as a category, far less harmful than combustible cigarettes. Further, most e-cigarette users are former or current users of combustible

⁴³ *Cf., R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 191 (2023) (“The FDA did not adequately address RJRV’s evidence that substantial health benefits would to adult and youth cigarette smokers alike who switched to menthol Vuse, while popularity among youth would remain low overall.”).

cigarettes, and, at least outside of New York City, the overwhelming majority of users of such products prefer flavored e-cigarettes. When one considers that most users of flavored e-cigarettes would, in all likelihood, otherwise be smokers of combustible cigarettes, it cannot be said that the gravity of the harm resulting from Demand Vape’s distribution of such products to Star Vape—a wholesaler of such products—outweighs the utility.

FDA-funded researchers have found that banning flavored e-cigarette products—as New York City has elected to do—results in an increased sale of 15 cigarettes for every 0.7 mL cartridge of flavored e-liquid not sold as a result of the flavor restriction. *See supra* note 12. The former director of FDA’s Center for Tobacco Products has also observed that “mass market exit of [e-cigarette] products would limit the availability of a potentially less harmful alternative for adult smokers seeking to transition or stay away from combustible tobacco products” and “could adversely affect the public health.”⁴⁴ And even among youth who illegally procure and use e-cigarettes, use is most strongly concentrated in those who had previously used cigarettes or other nicotine products.⁴⁵ (Indeed, this is likely part of the reason that, instead of serving as a “gateway” to cigarettes, ENDS are instead diverting users who would otherwise smoke cigarettes and leading

⁴⁴ *See* Declaration of Mitchell Zeller at 15, *Am. Acad. of Pediatrics v. FDA*, No. 8:18-cv-00883 PWG (D. Md. June 12, 2019), Doc. No. 120-1.

⁴⁵ Sokol NA, et al. High School Seniors Who Used E-Cigarettes May Have Otherwise Been Cigarette Smokers: Evidence From Monitoring the Future (United States, 2009-2018). *Nicotine Tob Res.* Oct 7 2021;23(11):1958-1961, <https://pubmed.ncbi.nlm.nih.gov/33991190/>; Jarvis M, et al. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey 2017-2019 reveal about high school e-cigarette use in the USA? *Qeios.* 2020/09/02 2020, <https://www.qeios.com/read/745076.5>; Action on Smoking and Health, Use of e-cigarettes among young people in Great Britain (2023), <https://ash.org.uk/uploads/Headline-results-ASH-Smokefree-GB-adults-and-youth-survey-results-2023.pdf?v=1684400380>. Indeed, one study found that 70% of British youth who currently use e-cigarettes had a history of cigarette smoking. Wang TW, Gentzke AS, Creamer MLR, et al. Tobacco product use and associated factors among middle and high school students-United States, 2019. *MMWR Surveill Summ* 2019;68(12):1–22, https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm#T6_down.

to faster rates of decline of youth and young adult smoking prevalence than were otherwise anticipated by public health officials.⁴⁶)

Because the City offers no evidence that Magellan and Demand Vape acted either unreasonably or with the intention of creating or contributing to any public nuisance, the City cannot satisfy its burden of proving a clear or substantial likelihood of success on its public nuisance claim.

2. The City fails to show that Magellan or Demand Vape were a “substantial factor” in causing the alleged public nuisance.

The City also has not shown that Magellan or Demand Vape were a “substantial factor” in causing the alleged public nuisance. To prove its public nuisance claim, the City must establish that Magellan and Demand Vape “participated to a substantial extent” in creating or maintaining the nuisance. *Suez Water N.Y., Inc. v. E.I. du Pont de Nemours & Co.*, 578 F. Supp. 3d 511, 545, 548 (S.D.N.Y. 2022) (quoting *In re MTBE Prods. Liab. Litig.*, 725 F.3d at 121). Whether sufficient causal connection exists depends on the level of participation and contribution by each defendant: a party that contributes in a remote way may be “simply too far removed from the nuisance to be held responsible for it,” *People v. Sturm, Ruger & Co.*, 309 A.D.2d 91, 104 (1st Dept. 2003), whereas a party whose conduct “remains the dominant and relevant fact without which the public nuisance would not have resulted where and under the circumstances it did,” *City of New York v. A-1 Jewelry & Pawn, Inc.*, 247 F.R.D. 296, 347 (E.D.N.Y. 2007), may be held liable.

⁴⁶ Jarvis M, et al. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey 2017-2019 reveal about high school e-cigarette use in the USA? *Qeios*. 2020/09/02 2020, <https://www.qeios.com/read/745076.5>; Meza R, et al. Trends in Tobacco Use Among Adolescents by Grade, Sex, and Race, 1991-2019. *JAMA Network Open*. 2020;3(12):e2027465-e2027465, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2773464>; Selya AS, et al. Trends in electronic cigarette use and conventional smoking: quantifying a possible ‘diversion’ effect among US adolescents. *Addiction*. 2021;116(7):1848-1858, <https://onlinelibrary.wiley.com/doi/full/10.1111/add.15385>.

For purposes of “substantial factor causation,” “substantial means that the act or omission had such an effect in producing the injury that reasonable people would regard it as a cause of the injury.” *Suez Water*, 578 F. Supp. 3d at 539 (quoting *In re MTBE Prods. Liab. Litig.*, 725 F.3d at 116). The cause cannot be “slight or trivial”; rather, there must be facts “indicating that it is reasonably probable, not merely possible or evenly balanced, that the defendant was the source of the offending product.” *Id.* (internal quotation marks and citations omitted). Relevant considerations include (1) the number of contributing factors for which the defendant was not responsible and the effect which each has in producing it; (2) whether the defendant contributed continuously up to the time of harm, or whether the “situation was acted upon by other forces for which the defendant is not responsible,” and (3) the lapse of time since the defendant’s contribution. *Suez Water*, 2023 U.S. Dist. LEXIS 48925, at *18. It is not enough that Magellan or Demand Vape may have introduced a product into the stream of commerce. *See Suez Water*, 578 F. Supp. 3d at 548-551 (dismissing public nuisance claim against manufacturer of chemicals because plaintiff failed to plead how the defendants directed or controlled the conduct that cause the alleged nuisance or had “specific knowledge of the mechanisms by which the product was being improperly handled”).

Again, rather than provide any specific evidence on how Magellan or Demand Vape contributed to the illegal procurement and use of flavored ENDS products by underage individuals to a “substantial extent” or were a “substantial factor” in creating or maintaining the public nuisance, the City essentially seeks to hold Defendants liable for the unlawful actions of third parties with which Defendants have no connection. The City has offered no evidence demonstrating that Defendants “not only had knowledge that [their] product[s] would be used in a manner that would create a nuisance, but also sold the product *directly and continuously* to the

person engaged in the nuisance-creating activity even after acquiring the knowledge that the person was creating a nuisance.” *Suez Water*, 578 F. Supp. 3d at 549. The City fails to offer evidence of any post-sale control, knowledge, or participation by Magellan or Demand Vape, including as to any retailer who purchased products from Demand Vape and then sold them to underage individuals.⁴⁷ Further, in response to the concerns raised by the City, Demand Vape has instituted a company policy prohibiting any sales of flavored e-cigarette or e-liquid products to any retailers located in New York City.⁴⁸ This fact alone fundamentally undermines the City’s claim that preliminary injunctive relief is justified, as to “enjoin future behavior, the government must show . . . that there is some reasonable likelihood that the violations may recur.” *Blue Ribbon Smoked Fish, Inc.*, 179 Supp. 2d 30, 50 (E.D.N.Y. 2001); accord *SEC v. Manor Nursing Ctrs, Inc.*, 458 F.2d 1082, 1100 (2d Cir. 1972).

Magellan and Demand Vape were, at best, far removed from the specific activity resulting in the procurement and use of flavored e-cigarette products by underage individuals. Instead, the *per se* unlawful actions of multiple other parties were contributing factors that more directly and proximately caused the resulting harm about which the City complains. To the extent that any

⁴⁷ The City’s contention in this respect is perhaps best crystallized by its claim that “[b]y supplying retailers with e-cigarettes it is certainly foreseeable that there will be sales to persons below the age of 21.” ECF 50 at 31. In short, the City claims that Defendants should both expect, and then be held liable for, widespread lawbreaking by completely unrelated third parties.

⁴⁸ Contrary to the City’s misstatements in its supporting memorandum, ECF 50 at 1, 19, 23, 32, Glauser *never* stated that Demand Vape intended “to ensure that retailers across New York can offer’ flavored e-cigarettes.” Rather, what Glauser *actually said* in his op-ed was: “The work my company does . . . ensures that retailers across New York can offer *their adult customers a vastly less harmful alternative to smoking combustible cigarettes*” (emphasis added). See <https://www.nydailynews.com/2023/10/07/eric-adams-unfair-attack-on-vaping-nyc-lawsuit-against-legal-companies-is-wrong/>. The difference is material. Given that the City places great emphasis on its misrepresentation of Glauser’s actual statement and reiterates that misrepresentation multiple times throughout its memorandum, the City’s misrepresentation cannot be construed as anything other than as intended to affirmatively mislead the Court.

retailer sold any e-cigarette products—flavored or unflavored—to an underage individual, the retailer violated multiple New York state and New York City laws in doing so. N.Y.C. Admin. Code § 17-706, N.Y. Pub. Health Law § 1399-cc(2); *see also* 21 U.S.C. § 387f(d)(5). If that retailer lacked a state dealer registration and license from the City, the retailer violated even more laws.⁴⁹ N.Y.C. Admin. Code § 20-561; N.Y. Tax Law § 1183. And, if an individual over 21 purchased the e-cigarette products at issue as a “straw man” and then turned around and sold or otherwise provided them to an underage individual, that adult also violated the same State and City laws cite above. The City adduces no evidence that either Magellan or Demand Vape knew about any such illegal sales to underage individuals involving any of Demand Vape’s customers, *compare* Glauser Decl., ¶ 18 (disclaiming any such knowledge), and thereby fails to satisfy the requirement that continuous contribution to a public nuisance must come *after* the defendant learned about the alleged nuisance. *Suez Water*, 578 F. Supp. 3d at 549.

The City’s position that Magellan and Demand Vape should be held liable for the use of flavored e-cigarette products by New York City youth when multiple unlawful acts by downstream parties were far more closely tied to the harm of which the City complains would eviscerate the causation requirement’s demand that Magellan and Demand Vape’s conduct be “the dominant and relevant fact without which the public nuisance would not have resulted.” *A-1 Jewelry & Pawn, Inc.*, 247 F.R.D. at 347.

Indeed, the evidence offered in support of the City’s motion undermines the City’s narrative. Magellan’s Hyde-branded flavored e-cigarettes were only observed in 7 out of 313 retail stores visited by the volunteers cited in the City’s motion. *See* ECF 50 at 5. Neither Magellan nor

⁴⁹ Demand Vape’s requirement that retailers based in New York State provide a copy of their dealer’s registration certificate before they are able to initiate their first order mitigates any concern that Demand Vape is selling to unlicensed retailers. Glauser Decl., ¶ 15.

Demand Vape sells any e-cigarette products, let alone flavored e-cigarettes, to *any* of the seven retailers specifically cited in the City’s motion. *See* ECF 50 at 10; Glauser Decl., ¶ 17. Similarly, Hyde-brand e-cigarettes were only observed at 15 of the 197 stores visited by the City’s investigator. *See* ECF 50 at 6-7. Empire Vape is not a customer of Magellan or Demand Vape, Glauser Decl., ¶ 17, and the Empire Vape invoice submitted by the City does not list a single Hyde product being sold to a retailer. *See* Exhibit O to Proshansky Declaration, ECF 42-2. And, as the City acknowledged in the Motion, Hyde e-cigarettes found during an inspection of Empire Vape were directly from China, and not from Magellan or Demand Vape. *See* ECF 50 at 24. Further, the one concrete example of allegedly continuous contribution to an alleged nuisance was sales by Demand Vape to a wholesaler that under New York City’s own regulations could lawfully possess and sell flavored e-cigarettes so long as it was to parties outside of New York City. *See* Exhibit S to Proshansky Declaration, ECF 42-2 (sales to Star Vape Corp).

The City’s theory of public nuisance and arguments as to “substantial extent” contribution and “substantial factor” causation would essentially apply strict liability to upstream parties for the actions of downstream parties, or even completely unrelated and disconnected parties, over whom they have no control. Adopting the City’s position would allow any manufacturer or upstream distributor to be held liable for an alleged public nuisance regardless of how attenuated their connection was to the claimed nuisance. Even though New York has not adopted an absolute rule barring liability for upstream manufacturers or distributors who do not carry on, control, or direct the nuisance-creating activity like other jurisdictions,⁵⁰ the City’s position “violates the principle

⁵⁰ *See, e.g., City of Bloomington, Ind. v. Westinghouse Elec. Corp.*, 891 F.2d 611 (7th Cir. 1989) (affirming dismissal of nuisance claim where plaintiff failed to set “forth facts from which it could be concluded that Monsanto retained the right to control the PCBs beyond the point of sale to Westinghouse” and thus there was “no basis upon which to conclude that Monsanto” was liable); *Tioga Pub. Sch. Dist. No. 15 v. U.S. Gypsum Co.*, 984 F.2d 915, 920 (8th Cir. 1993) (finding

that New York courts will not extend liability to anyone contributing in some way or another to a nuisance or its maintenance ‘no matter how far removed from defendants’ lawful business practice the harm is felt.’ *Suez Water*, 578 F. Supp. 3d at 551.

3. The City fails to show that the mere distribution of flavored e-cigarettes and e-liquids is, on balance, injurious to the health of the City’s citizens when compared to the alternative of smoking combustible cigarettes.

In support of its motion, the City asserts that “there is injury to the public health of its citizens through the proliferation of e-cigarettes and e-liquids because those products incontrovertibly endanger the health of the City’s youth.” ECF 50 at 26. However, as noted above, the City’s position and supporting evidence wholly ignore the harm reduction potential of these products when weighed against the combustible cigarettes which many users of such products would otherwise consume—a countervailing public health benefit.⁵¹

nuisance claim against asbestos manufacturer was improperly submitted to a jury when the manufacturer was no longer in control of the asbestos-containing product at the time it became a nuisance); *In re Methyl Tertiary Butyl Ether (“MTBE”) Prods. Liab. Litig.*, No. 1:00-1898, 2021 U.S. Dist. LEXIS 145123, at **63-64 (S.D.N.Y. Aug. 2, 2021) (dismissing Pennsylvania’s public nuisance claims for a second time to the extent they were premised on the defendants’ mere manufacture or distribution of MTBE or MTBE gasoline as they failed to allege defendants had control over the site from which the alleged nuisance originated); *In re Syngenta AG MIR 162 Corn Litig.*, 131 F. Supp. 3d 1177 (D. Kan. 2015) (dismissing private nuisance claim against manufacturer and seller of genetically modified seeds for allegedly contaminating the plaintiffs’ corn supply because defendant did not have continuing control over the product after sale); *In re Dicamba Herbicides Litig.*, 359 F. Supp. 3d 711, 729 (E.D. Mo. 2019) (dismissing nuisance claim against manufacturer as it lacked control of product after sale to third parties).

⁵¹ It bears underscoring that *City of N.Y. v. Artisan Vapor Franchise LLC*, No. 19-cv-5693, 2020 U.S. Dist. LEXIS 205315 (E.D.N.Y. Nov. 2, 2020), upon which the City heavily relies, was a report and recommendation on a motion for default judgment, meaning that no arguments were advanced against the City’s narrative that there existed an “‘epidemic of underage e-cigarette use’ which endangers the health of New York City youth” in a manner comparable to combustible cigarettes, *id.* at **5-6 (citing *City of New York v. Milhelm Attea & Bros., Inc.*, 550 F. Supp. 2d 332, 350-51 (E.D.N.Y. 2008)).

As noted above, e-cigarettes in general, including flavored e-cigarettes, contain far fewer harmful and potentially harmful constituents than combustible cigarettes and have not been proven to act as a “gateway” to youth initiation of combustible cigarette use. Rather, the scientific evidence suggests that, among both youth and adults, many regular users of e-cigarettes would otherwise smoke combustible cigarettes. Indeed, the effect of flavor bans in jurisdictions like New York City has been to actually *increase* the number of combustible cigarettes sold—an outcome that is indisputably at odds with protecting the public health. Thus, in addition to the reasons explained above, the City has not carried its burden of showing a substantial likelihood of success on its claim that, at the population level and on net, the availability and use of e-cigarettes is injuring the public health of the City’s citizens.

For the foregoing reasons, the City has failed to show a substantial likelihood of success on its public nuisance claim as to any of the Defendants.

II. THE BALANCE OF EQUITIES WEIGHS AGAINST AN INJUNCTION

Continuing its over-the-top attacks on Defendants, the City compares them to a “drug cartel,” while falsely suggesting that their products are “intrinsically illegal.” Even New York State disagrees with that position and allows the possession of flavored electronic cigarettes as well as their sale except at retail to individual consumers. *See* N.Y. Pub. Health Law § 1399-m-1. Similarly, as noted above, the City allows wholesalers to possess and sell flavored e-cigarettes so long as such sales are to an “entity located outside the City of New York.” 24 R.C.N.Y. § 28-02(b). The injunction sought by the City would essentially override both State and City law, stripping not only retailers, but also wholesalers of the ability to possess flavored e-cigarettes for purposes of sale outside the City.

Additionally, while monetary damages are typically not considered “irreparable injury,” such financial losses are irreparable when they are unrecoverable, such as when a governmental

body causing the loss enjoys sovereign immunity. *See Regeneron Pharms., Inc. v. United States HHS*, 510 F. Supp. 3d 29, 39 (S.D.N.Y. 2020) (“[W]here a plaintiff cannot recover damages due to sovereign immunity, monetary loss may amount to irreparable harm.”) (citing *United States v. New York*, 708 F.2d 92, 93 (2d Cir. 1983)). Here, Defendants would be unable to recover for the financial losses that would result from being enjoined from selling to lawfully operating wholesalers and distributors simply because they are in New York City. *See Axt v. Hyde Park Police Dep’t*, 162 A.D.3d 728, 729 (2d Dept. 2018) (“Generally, a municipality may not be held liable to a person injured by the breach of a duty owed to the general public” (internal quotations omitted)).

Moreover, even without an injunction, the City can act against the parties actually responsible for any alleged nuisance – New York City retailers that fail to comply with State and City law. As the City makes clear in its memorandum and supporting declarations, many grounds exist to pursue action against retailers that flout State and City laws, whether by selling e-cigarettes without a license or dealer registration in violation of N.Y.C. Administrative Code § 20-561 and New York Tax Law § 1183; selling e-cigarettes to individuals under 21 years old in violation of N.Y.C. Administrative Code § 17-706 and N.Y. Public Health Law § 1399-cc(2); or selling flavored e-cigarettes at retail at all in violation of N.Y.C. Administrative Code § 17-715 and N.Y. Public Health Law § 1399-mm-1. The City’s own papers underscore that it has more than sufficient evidence to pursue such retailers, and even if Defendants were enjoined from selling their products to any customers in New York City, those retailers would still be able to (as they are now) acquire flavored e-cigarette products from other sources. Indeed, co-defendant Empire Vape is not a customer of either Magellan or Demand Vape, yet possessed flavored e-cigarettes and even

apparently obtained Hyde-branded e-cigarettes directly from China, completely circumventing Defendants' distribution controls.

CONCLUSION

For the foregoing reasons, the Court should deny the City's motion for preliminary injunction as to Magellan, Demand Vape, Glauser, and Hashagen.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of December, 2023, I caused the foregoing to be electronically filed with the Clerk via the Court's ECM/ECF system and thereby electronically served on all counsel of record.

_____/s/ Eric N. Heyer_____